OFFICE OF RESEARCH AND DEVELOPMENT LETTER

SOLICITATION FOR PROPOSALS TO ESTABLISH REHABILITATION RESEARCH AND DEVELOPMENT CENTERS

- 1. This Information Letter announces the opportunity for Department of Veterans Affairs (VA) medical facilities to submit proposals for establishing Rehabilitation Research and Development (RR&D) Centers with focus on research in high priority areas relevant to the rehabilitation needs of veterans. *NOTE:* Required formats and instructions for submitting applications are provided in Attachments A and B.
- 2. This solicitation will not support Centers based predominantly at non-VA sites.
- 3. Funding for three VA RR&D Centers expires 09/30/04. Each of these Centers must submit an application for competitive renewal. Applications from new sites will be reviewed concurrently. Funding for up to an additional 3 new VA RR&D Centers is anticipated, for a total of up to six Centers to be funded with this review.
- 4. VA RR&D Centers are intended to be a resource, first, for the veterans served by VA, especially by the host VA medical facility and, second, for the rehabilitation community at large. They are expected to provide cutting edge solutions to the issues of chronic impairment. It is anticipated that Centers will establish and cultivate a community of VA clinical scientists and scholars within the VA healthcare system for the purpose of pursuing specific research objectives in accord with a well reasoned 5-year plan. Centers are to develop an integrated thematic research core as a unifying focus of research activities. They are expected to:
- a. Become nationally recognized "Centers of Excellence" in a selected area of research relevant to veterans with disabilities.
- b. Successfully leverage core support funding through nationally competed and scientifically reviewed funding vehicles: VA investigator-initiated programs, Federal granting agency programs, private foundation awards, and collaborations with commercial partners.
- c. Mentor and support young investigators, both clinician and non-clinician scientists, through pre- and post-doctoral programs and recruit them into VA.
- d. Nurture strong interactive relationships with the appropriate VA medical facility clinical service providers engaged in rehabilitation, long-term management of impairment, and overall quality of life issues.
- e. Maintain collaborative partnerships of mutual benefit to VA, the VA medical facility, and the supporting community institutions (e.g., schools of medicine, allied health sciences and/or engineering as applicable to research focus).

- f. Facilitate effective information dissemination for a broad spectrum of audiences.
- g. Foster the integration of research findings into clinical practice throughout the health care delivery system.
- h. Actively participate in the national consortium of VA RR&D Centers to strengthen natural collaborative bonds and advance VA RR&D in the scientific community and national consciousness.
- 5. Current foci of RR&D Centers are: Vision Impairment and Aging (*Atlanta*); Innovative Visual Rehabilitation (*Boston*); Rehabilitation Outcomes—Stroke (*Gainesville*); Bone & Joint (*Palo Alto*); Amputation, Prosthetics and Limb Loss Prevention (*Seattle*); Rehabilitative Auditory Research (*Portland*); Functional Electrical Stimulation (*Cleveland*); Medical Complications of SCI (*Bronx*); and Functional Recovery in SCI (*Miami*).
- 6. Centers up for competitive renewal are focused on Brain Injury Rehabilitation (*Gainesville*); Wheelchair and Related Technology (*Pittsburgh*); and Restoration of SCI & Multiple Sclerosis (*West Haven*).
- 7. In addition, RR&D funds three Research Enhancement Award Programs (REAPs) in Audiology (*Mountain Home*); Tissue Engineering (*Boston*); and Technology for "At-Risk" Patients (*Tampa*).
- 8. VA RR&D emphasizes and funds research in the following broad priority areas: Prosthetics, Orthotics and Orthopedic Rehabilitation; Neurological Dysfunction and SCI Restoration and/or Rehabilitation and/or Medical Complications; Geriatric Rehabilitation; Visual and Hearing Impairment Rehabilitation; Rehabilitation Engineering; Rehabilitation Outcomes. Proposed research foci must be in a rehabilitation area of importance to the veteran population with evidence of near term applicability. In addition to areas already funded, encouraged areas of new emphasis include, but are not limited to:
 - a. Technologies for Successful Aging.
- b. Evidence based Rehabilitation (Rehabilitation Outcomes) and Physiologic Techniques for Validating Outcomes.
- c. Creative Approaches to NeuroRehabilitation and/or Neurologic Repair: Stroke, Multiple Sclerosis, Parkinson's Disease, Degenerative Neurologic Disorders.
 - d. Robotics: Neuro; Therapeutic; Prosthetics.
 - e. Telerehabilitation.
 - f. Psycho-Social Rehabilitation for Chronic Mental Disease.
 - g. Traumatic Brain Injury.

- h. Neuropathic Pain.
- i. Innovative approaches to Prosthetic Development.
- 9. Any VA medical facility (or consortium of VA medical facilities) with significant rehabilitation research capacity and with well-established academic partnerships is encouraged to apply. Maximum RR&D awards of core funding will be up to \$850,000 annually, with required competitive renewal on a 5-year cycle. Up to \$7,000.00 per year of the award can be requested for VA travel.
- 10. Each Center will have a Director and Associate Director for Research with doctoral degrees and at least a 5/8th VA appointment. Either the Director or Associate Director must be a clinician with medical care funds committed by the host VA medical center in support of clinician salary. The medical and scientific leadership team is expected to:
- a. Identify research goals and objectives within a given focus area and direct research plans towards achievement of specified goals and objectives. Research plans need to include collaborative activities
- b. Develop a 5-year research program with specific aims directed toward new discoveries that have the potential to impact on clinical practice.
- c. Achieve maximal administrative efficiencies, control and reporting capabilities, project monitoring, and leveraging of limited core support funds at local and national levels.
- d. Support the growth and enhancement of a vigorous and creative "learning environment." Maintain Information Dissemination Activities that promote findings from VA RR&D Centers.
- 11. RR&D Center proposals will be scientifically reviewed for merit to objectively determine relevance of the proposed research to the veteran population, capability of applicant to meet intended outcome of proposed research program, and potential contribution of proposed research to the field of rehabilitation, long-term management of impairment, and overall quality of life issues for veterans with disabilities. Criteria for review and evaluation are:
 - a. Strength of Proposed Research Focus. This includes the:
 - (1) Relevance to veteran population,
 - (2) Relationship of proposed research activities to announced research focus,
 - (3) Potential of proposed research to produce new and useful information,
 - (4) Clarity and ability to execute the research plan, and
 - (5) Contribution to overall VA RR&D portfolio.

- b. Effectiveness of Operating Plan. This includes the:
- (1) Ability to achieve intended research outcomes,
- (2) Ability to coordinate the proposed collaborations and evidence of their benefit to VA and veteran healthcare.
 - (3) Feasibility of evaluation and quality assurance methods,
 - (4) Sufficient coverage of all required disciplines,
 - (5) Ability to build research capacity within VA, and
 - (6) Effectiveness of plan to disseminate research findings.
 - c. Adequacy of Resources. This includes the:
- (1) Scientific strength of current VA Research and Development (R&D) Program, especially in rehabilitation research,
 - (2) Vitality of rehabilitation clinical base within VA medical facility,
 - (3) Support and demonstrated commitment of VA medical facility(s) and cited affiliations,
 - (4) Demonstrated scientific, engineering, and/or medical leadership of key personnel at VA,
 - (5) Evidence of VA-based core of investigators, and
 - (6) Adequacy of VA facilities and equipment.
 - d. Budget and Cost Effectiveness. This includes the:
 - (1) Ability to support program activities,
 - (2) Reasonable costs, and
 - (3) Appropriateness and detail of subcontract budget (if required).
- 12. General guidelines for applicants are:
 - a. All Center funding awards are contingent on availability of funds.
- b. All applicants must submit a Letter of Intent (LOI) to Apply by November 1, 2002 (see Att. A). LOIs must be directed through the ACOS for Research and include :
 - (1) Names of key investigators,

- (2) Certification from the facility that the principal investigators have at least 5/8th VA appointments, and
- (3) Certification that space will be provided at the VA facility to support the proposed center.
- c. The R&D Committee before submission must review all applications. If a Center is awarded, then an appropriate response from Human Subject, Animal Safety, and BioSafety Subcommittee reviews and approval will be required before September 1, 2003.
- d. Applicant sites may be a single VA medical facility or a consortium of collaborating VA medical facilities. Consortium applicants must identify a lead site with a well-established academic partnership. Organizational relationships and responsibilities of consortia are to be clearly delineated.
- e. Scientifically approved proposals will require administrative site visits in advance of making definitive funding determinations.
- f. The Director and Associate Director must be eligible to receive VA research support (eligibility must be established prior to submission of the proposal).
- g. Annual (non-competing) progress reports for the Center will be reviewed administratively by RR&D Service to monitor performance against stated program plans. *NOTE: Unsatisfactory performance will result in probationary status or termination of funding.*
- 13. The timeline for proposal submission, review, and award is:
 - a. Letters of Intent: November 1, 2002.
 - b. Proposals due in VHA Central Office (see Att. B): March 15, 2003.
 - c. Review: July 2003.
 - d. Administrative site visits: August, 2003.
 - e. Final Notification of Awards: September 15, 2003.
 - f. Funding (for new Centers) Begins: October 1, 2003.

14. Questions concerning this solicitation for proposals may be directed to: Laura Bowman, RR&D Service, at 202-408-3680 or e-mail, bowlau@mail.va.gov.

S/ James F. Burris, M.D. Acting Chief Research and Development Officer

Attachments

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ATTACHMENT A

INSTRUCTIONS FOR SUBMITTING A LETTER OF INTENT (LOI) TO ESTABLISH REHABILITATION RESEARCH AND DEVELOPMENT CENTERS

1. SCOPE

- a. The Letter of Intent (LOI) Review. The LOI review serves to:
- (1) Confirm that each proposal forwarded in response to this solicitation is within the announced intent and scope of Rehabilitation Research and Development (RR&D) Centers.
- (2) Identify and resolve major problems such as Department of Veterans Affairs (VA) investigator eligibility and VA off-site research issues prior to allowing the submission of a full proposal.
- b. <u>Due Date.</u> LOIs to submit proposals to establish RR&D Centers are due on <u>November 1</u>, <u>2002</u>. LOI's received after this date will not be reviewed. Proposals will not be accepted without an approved LOI.
- c. <u>Review Process.</u> LOIs will be reviewed for scientific merit, relevance to veterans' needs, RR&D Service priority areas, and whether the proposed research advances the knowledge base of rehabilitation research. Written notification regarding results of the review will be sent within 6weeks through the Office of the Associate Chief of Staff (ACOS) for Research and Development (R&D). An investigator must have an approved LOI in order to submit a proposal to establish a RR&D Center for review.
- d. <u>Eligibility.</u> RR&D Service is an intramural research program. All applicants (i.e., the Principal Investigator (PI) and any CO-PI) for VA research funds must hold a minimum 5/8th VA salaried position. Individuals with less than a 5/8th VA appointment are encouraged to seek at least a 5/8th VA official appointment. Investigators wishing to join the VA, must indicate so in writing within the context of the LOI. Should an applicant's proposal be approved, funding will not be forwarded until the VA appointment is secured.
- e. <u>Off-Site Research.</u> As an intramural program, it is VHA policy to ensure that VA-funded research is performed within VA medical centers. Effective January 15, 1998, any investigator who applies for VA research support and who has performed or seeks permission to perform research outside of VA medical centers, VA-owned, or VA-leased space must request a waiver from RR&D Service to perform the research off-site. The request for a waiver is to accompany the LOI and must be received no later than 60 days prior to the proposal submission due date (refer to VHA Handbook 1200.16 further information).

2. FORMAT

a. VA Form 10-1313-13, Cover Sheet, must be submitted with a LOI. Check applicable categories in each box and type in all requested information. *NOTE:* In Box #2, marked Program Area, state priority area and specify "Center."

- b. The information contained in the LOI <u>can be up to three pages of text</u>, plus one page of cited references. An additional page describing the PI's experience in the proposed research area is allowed.
 - c. Use at least 1-inch margins on all sides and at least 11 point.
- (1) Type in a font that is easy to read and reproduce. Any LOI using low quality or small print will be returned without review.
- (2) Use **bold** type for all major section headings, and separate major sections with a double space.
- d. <u>Text Pages (maximum of three).</u> At the top of each page, type PI's name and Project Title and date. In the following order, state:
- (1) **Purpose.** List the goals and specific objectives of the proposed program of research (use approximately 1/4 page).
 - (2) **Background.** (use approximately 1/2 page).
- (a) State the scientific rationale for the proposed research and its relationship to other major research findings.
 - (b) Explain how this research will advance knowledge in rehabilitation research.
- (c) Describe the significance of the research and how it relates to RR&D priority areas. Indicate how this research directly benefits veterans and how it contributes to the quality of services provided by VA.
- (3) **Expected Outcomes or Products.** Describe the outcome in terms of expected time and resources needed to develop a Center program in this area (use approximately 1/4 page).
- (4) **Proposed Areas of Study:** Outline the proposed areas of study (use approximately one page).
- (a) Identify VA patient population, sample size and rationale for inclusion or exclusion of population served; (include women and members of diverse ethnic and racial groups).
 - (b) Identify key issues that may have an impact on the success of the Center.
- (c) Specify if proposed research will be with animals and if so what is the time frame for clinical application.
 - (d) Indicate implications for technology transfer and potential for replication.

- (5) **Participants.** Identify PI, CO-PI(s), co-investigators, and consultants; state their areas of expertise.
- (6) **Resource and Budget.** RR&D Centers are funded for 5 years with up to \$850,000 a year. Up to \$7,000 per year of the award may be used for VA travel.

e. Project History

- (1) Indicate if this Center is new, a continuation of an existing Center (years funded), or related to a previously disapproved Center submission.
 - (2) Indicate the Project number, title, and date of the previous related submission.
- f. **Research Site.** State the name of the facility where the majority of research (patients and laboratory work) will take place (Item 6 on VA Form 10-1313-13, Cover sheet).

3. SUBMITTING THE LOI

Both a hard copy **and** an electronic copy of the LOI are required.

- a. The LOI must be signed either the ACOS for R&D, R&D Coordinator, or appropriate designee. *NOTE:* LOIs from R&D regionalized facilities will not be accepted without being processed through the appropriate research office.
- b. The signed, original LOI must be sent to the following address by November 1, 2002. **NOTE:** Prior approved e-mail or facsimile copies will be accepted, but the original must still be mailed.

Letters of Intent Coordinator Program Analysis and Review Section (122P) Rehabilitation Research and Development Service Department of Veterans Affairs 810 Vermont Avenue, NW Washington, DC 20420

c. Electronic Submission is Required for LOIs. Visit

<u>http://www.vard.org/guid/elecsub2.htm</u> to view the instructions for electronic submission of proposals. Electronic LOIs can be emailed to <u>pars@vard.org</u>.

4. INQUIRIES AND ADDITIONAL INFORMATION

Inquiries regarding the Center solicitation should be directed to Terri Carlton at (202) 408-3675 or via email at terrilynn.carlton@hq.med.va.gov.

ATTACHMENT B

INSTRUCTIONS FOR SUBMISSION OF APPLICATION REHABILITATION RESEARCH AND DEVELOPMENT CENTERS

- 1. <u>General.</u> Whether preparing a first-time or competing renewal application, the proposal must be well organized, clearly presented, and complete without presumption of reliance on previous proposal submissions or of assumed public common knowledge.
- **2.** <u>Forms.</u> Department of Veterans Affairs (VA) Forms 10-1313-1 through 8, Merit Review Application, are to be used for Center proposals. Forms are available through each VA facility's Office of Associate Chief of Staff (ACOS) for Research and Development (R&D), or equivalent.

3. Content Order

- a. A VA Form 10-1313-1, Merit Review Application. Provide brief identifying information. Items which may require clarification are:
 - (1) Items 1, 2, and 4. Leave blank.
 - (2) Item 3. Review group should be identified as "Center."
 - (3) <u>Items 5 and 6.</u> For applications proposing consortia, identify lead site.
- (4) <u>Item 9.</u> List the Center Director as Principal Investigator (PI), Associate Director as Co-Principal Investigator (Co-PI).
 - (5) Item 10. Center the title; it needs to be short and easily identify program and its focus.
 - (6) Item 11. Amount requested should be for fiscal years.
- b. **VA Form 10-1313-2, Summary Description of Program.** Provide a brief narrative scientific abstract not to exceed 500 words. List key words that best describe the program's scientific disciplines and research focus.
 - c. Table of Contents
 - d. Approved Letter of Intent (LOI)
- e. Narrative should not exceed forty pages (including figures and tables) with no more than five additional pages for references. *NOTE:* This page limit does not include VA forms or appendixes. Components expected to be contained in the narrative and <u>suggested</u> page lengths include:
- (1) A discussion of intended research directions and the proposed methods for implementing them (eight to ten pages).

- (a) Show how each group of related research will contribute sequentially or cumulatively to the resolution of practical rehabilitation problems.
- (b) Discuss focus in relation to health care needs of the veteran population, VA medical center and/or Veterans Integrated Service Network (VISN) mission, and the mission of VA's R&D.
 - (c) Describe how current local programs and affiliations complement focus.
 - (d) Review current status of nation's research in this area.
 - (e) Identify expected outcomes of proposed research direction.
 - (2) Discuss available resources (three to five pages).
 - (a) Identify clinical activities at the hospital that would provide a base for research.
- (b) Discuss current Rehabilitation R&D Program and highlight successful investigations in this area.
 - (c) Describe available VA physical facilities and program equipment.
- (d) Identify academic affiliation contributions in the areas of personnel, equipment and opportunities for learning.
- (3) Identify three to five lines of research and detail proposed scientific protocol, including state of research in the field, hypotheses, and proposed study methods. (fifteen to twenty-five pages)
- (4) Outline the present or proposed Center organization and staffing plan showing lines of authority and communication and describing operational responsibility (three to five pages).
 - (a) Explain how components will interface.
- (b) Discuss planned interaction with university and other community affiliations, showing purpose and mutual benefit of interaction.
- (c) Outline any planned formal mechanisms for information dissemination. Detail program evaluation and quality assurance mechanisms.
 - (d) Identify administrative controls.
- (e) Justify and include a copy of all formal agreements with non-VA institutions in Appendixes.

- f. VA Form 10-1313-3, Current Funds and First Year Request for Program, and VA Form 10-1313-4, Estimated Expenses of Program. These forms are to be used to submit proposed 5-year budget.
- g. VA Forms 10-1313-5, Investigator's Biographic Sketch, and VA Form 10-1313-6, Investigator's Bibliography. These forms are to be used to provide biographical sketches and a list of <u>up to ten</u> recent or significant publications for each of the Center's key VA and non-VA collaborating staff. Include <u>up to five</u> manuscripts reprints, which the PI feel best reflect work in proposed area, may be included as appendixes.
- h. VA Form 10-1313-7, Investigator's Total VA and Non-VA Research Support and VA Form 10-1313-8, Summary Statement Abstract and Budget Summary. These forms are to be used to list each person's current and pending total VA and non-VA research support.
- **4. Appendixes.** Appendixes are to be identified and labeled.
- a. Include letters of commitment and memoranda of understanding with collaborating institutions as appendices. A letter of commitment from VA medical facility Director and a letter of approval from R&D Committee are required for review.
- b. For consortium applications, a letter from each participating facility's Director and R&D Committee is to be included.

NOTE: Letters of support from elected officials are not be solicited nor included.

- **5.** <u>Authorization To Share Materials For Review</u>. It is expected that VA and non-VA reviewers will review proposals. Append the following statement, signed by the PI and Co-PI: "VA is authorized to share copies of all materials included in this application, for the purpose of scientific merit review."
- **6. <u>Submission.</u>** Submit the original application plus 20 copies of the proposal to: Rehabilitation Research and Development Service (122A), Office of Research and Development, Department of Veterans Affairs, 810 Vermont Avenue, NW, Washington, DC 20420
- a. Copies are to be duplicated back to back. With the exception of special forms, standard 8 1/2" x 11" white paper is to be used. Proposals are to be typed in no less than 12 point type, single-spaced with a 1 inch binder margin on all edges. Consecutively number pages in lower right corner.
- b. Proposals received after March 15, 2003, will not be reviewed. Proposals will not be accepted without an approved LOI. LOIs received after November 1, 2002, will not be accepted.